UNITED STATES DISTRICT COURT RECEIVED DISTRICT OF NEW JERSEY

RICHARD PENDOLPHIA, on behalf of Laborers Tri-County Pension Fund, derivatively on behalf of Schering-Plough Corp.,

Plaintiff,

٧.

HANS W. BECHERER, RAUL E. CESAN; HUGH A. D'ANDRADE; REGINA E. HERZLINGER; RICHARD J. KOGAN; ROBERT P. LUCIANO; EUGENE R. MCGRATH; DONALD L. MILLER; BARCLAY H. MORLEY; CARL E. MUNDY; RICHARD J. OSBORNE; DAVID H. KOMANSKY; PATRICIA T. RUSSO; ROBERT F. VAN OORDT; ARTHUR F. WEINBACH; AND JAMES WOOD,

Defendants,

and

SCHERING-PLOUGH CORPORATION, a New Jersey Corporation,

Nominal Defendant

MAR 2 1 2001

WILLIAM T. WALSH, CLERK

CIVIL ACTION NO.

(Shareholder Derivative Action)

JURY TRIAL DEMANDED

VERIFIED DERIVATIVE COMPLAINT FOR BREACH OF FIDUCIARY DUTY

FILED

VERIFIED DERIVATIVE COMPLAINT

Plaintiff, maintains his offices at 1269 Sans Souci Parkway, Wilkes-Barre, PA 18703, by and through his undersigned counsel, on personal knowledge as to himself and his own acts and information and belief as to all other matters based upon an investigation by plaintiff's counsel alleges for his derivative complaint as follows:

JURISDICTION AND VENUE

- This derivative action is brought pursuant to Rule 23.1 of the Federal 1.
- Plaintiff Richard Pendolphia brings this action on behalf of Laborers Tri-Rules of Civil Procedure. County Pension Fund ("The Fund" or "plaintiff"). Plaintiff is a citizen of the None of the defendants is a citizen of Commonwealth of Pennsylvania. The nominal defendant, Schering Plough, is a New Jersey corporation. The amount in controversy exceeds \$75,000, exclusive interest and Pennsylvania. costs. This Court has diversity jurisdiction over this action pursuant to 28 U.S.C. §1332.
 - This action is not brought collusively to confer jurisdiction on this Court which it would not otherwise have. Schering is headquartered in this district and the Company and the defendants are subject to personal jurisdiction in this district. Venue is proper in this district because some or all of the events, actions and failures to act giving rise to the claims asserted herein occurred in this district.

THE PARTIES

Plaintiff Richard Pendolphia brings this action on behalf of Laborers Tri-County Pension Fund ("The Fund" or "plaintiff"). The Fund is and has been a shareholder of Schering-Plough Corporation ("Schering" or the "Company") since August 7, 1991 and has continuously held Schering stock throughout the relevant period alleged herein to the present.

. . <u>1</u>.

DEFENDANT OFFICERS

- Defendant Richard J. Kogan ("Kogan") is and has been the Chairman of Schering's Board of Directors and Schering's Chief Executive Officer since November 1998. Before that time, from January 1996 to November 1998, Kogan was the President and Chief Executive Officer of the Company. He is also a director of Colgate-Palmolive Company and The Bank of New York Company, Inc.
 - Defendant Raul Cesan ("Cesan") is and has been the President, Chief Operating Officer and a director of Schering since November 1998. From September 1994 through November 1998, defendant Cesan was Schering's Executive Vice President - Pharmaceuticals. He is also a director of The New York Times Corporation, and a member of the Healthcare Leadership Council and the Healthcare
 - Defendant Hugh A. D'Andrade ("D'Andrade") was the Vice Chairman Institute of New Jersey. and Chief Administrative Officer of Schering from January 1996 to at least October 2000. D'Andrade was the Company's Executive Vice President - Administration from January 1985 to December 1995. Defendant D'Andrade reportedly retired from Schering as of December 31, 2000 and is no longer a member of Schering's Board of Directors. Schering does not currently list the title of Chief Administrative Officer among its corporate officers in its Annual Report for 2000.

AUDIT COMMITTEE DIRECTORS

, a 6

- Defendant Hans W. Becherer ("Becherer") is and has been a member of Schering's Board of Directors since 1989. During that time, defendant Becherer was a member of the Finance, Compliance and Audit Committee of Schering's Board of Directors at least from 1998 to the present. He is also a member of the board of directors of Honeywell, Inc. and J.P. Morgan Chase & Co.
 - Defendant Barclay H. Morley ("Morley") is and has been a member of Schering's Board of Directors since 1987. During that time, defendant Morley was a member of the Finance, Compliance and Audit Committee of Schering's Board of Directors at least from 1998 to the present. Since 1997, he has been a Board of Director of The Bank of New York Company, Inc. He is also the former chairman and chief executive officer of Stauffer Chemical Company.
 - Defendant Richard J. Osborne ("Osborne") is and has been a member of Schering's Board of Directors since 1988. During that time, defendant Osborne was a member of the Finance, Compliance and Audit Committee of Schering's Board of Directors at least from 1998 to the present. He is the non-executive chairman and director of Datawatch Corporation, a director of BFGoodrich Company, Birmingham Steel Corporation, NAACCO Industries, Inc. and The Tinker
 - Defendant Robert F. Van Oordt ("Van Oordt") is and has been a member Foundation. of Schering's Board of Directors since 1992. During that time, defendant Van Oordt was a member of the Finance, Compliance and Audit Committee of Schering's Board

of Directors at least from 1998 to the present. He is also Chairman and Chief Executive Officer of Rodamco Continental Europe N.V.

- Defendant Arthur F. Weinbach ("Weinbach") is and has been a member of Schering's Board of Directors since 1999. During that time, defendant Weinbach was a member of the Finance, Compliance and Audit Committee of Schering's Board of Directors at least from 1999 to the present. He is also Chairman and Chief Executive Officer of Automatic Data Processing, Inc. a provider of computerized transaction processing, data communication and information services.
 - Defendant Regina E. Herzlinger ("Herzlinger") is and has been a director of Schering since 1992. In Schering's Annual Report to Shareholders for 2000, defendant Herzlinger is listed as a member of the Finance, Audit and Compliance Committee. He is also a board of director of Cardinal Health, Inc. C.R. Bard, Inc., Deere & Company and Nanogen, Inc.

OTHER DEFENDANTS

- Defendant David H. Komansky ("Komansky") is and has been a director of Schering since October 25, 2000. Since 1997, he had been Chairman and Chief Executive Officer of Merrill Lynch & Co., Inc. During 2000 and continuing to the present, Merrill Lynch & Co., Inc. has provided to Schering investment banking, financial advisory and other services,
 - Defendant Robert P. Luciano ("Luciano") is and has been a director of Schering since 1978. He is also a director of Honeywell, Inc., C.R. Bard, Inc. and Merrill Lynch & Co., Inc.

- Defendant Eugene R. McGrath ("McGrath") is and has been a director of Schering since 2000. Since 1997, he has been Chairman of the Board, President and Chief Executive Officer at Consolidated Edison, Inc. He has been associated with Consolidated Edison company since 1963.
 - Defendant Donald L. Miller ("Miller") is and has been a director of Schering since 1997. He is also a director of The Bank of New York Company, Inc.
 - Defendant Carl E. Mundy ("Mundy") is and has been a director of Schering since 1995. Since 1999, he has been a board of director at General
 - Patricia F. Russo ("Russo) is and has been a director of Schering since Dynamics Corporation. 1995. She is also a director of Xerox Corporation. Currently, she is also Chairman of the Board at Avaya, Inc. From 1993 to 1997, she served as president of the Lucent Technologies businesses that now form the core of Avaya.
 - Defendant James Wood ("Wood") is and has been a director of Schering since 1987. He is currently the Chairman and Board of Director of Great Atlantic & Pacific Tea Company, Inc. He is also a director of Datawatch Corporation.

NOMINAL DEFENDANT

Nominal defendant Schering is a New Jersey corporation with its headquarters located in Madison, New Jersey. Schering is a holding company for subsidiaries engaged in the discovery, development, manufacturing and marketing of pharmaceutical products throughout the world. Among the Company's most noted products are prescription allergy medicines, Claritin and Nasonex. Schering has three basic product lines: Prescription - allergy/respiratory, anti-infective and anti-cancer; Dermatologicals; and Cardiovasculars.

- Finance, Audit and Compliance Committee of the Board and/or executive and managerial positions, defendants, pursuant to New Jersey law, owed the Company and its stockholders fiduciary obligations of candor, fidelity, trust, and loyalty, and are and were required to use their ability to control Schering in a fair, just and equitable manner, as well as to act in furtherance of the best interests of Schering and its stockholders. In addition, while they occupied their directorship, defendants owed Schering the fiduciary duty to exercise due care and diligence in the management and administration of the affairs of the Company and in the use and preservation of its property and assets.
 - 23. To discharge the aforesaid duties under New Jersey law, defendants were required to exercise reasonable and prudent supervision over management and the policies, practices, controls and financial affairs of the Company pursuant to their fiduciary obligations to use the same care and diligence as would an ordinary prudent person in a like position. Defendants were required, among other things:
 - (a) To, in good faith, manage, conduct, supervise and direct the business and affairs of Schering carefully and prudently and in accordance with the laws of New Jersey, the laws of the United States and the Company's own charter and by-laws;

- (b) To neither violate nor knowingly permit any officer, director or employee of Schering to violate applicable federal and state laws, rules and regulations or any Company rule or regulation;
- (c) To remain informed as to the status of Schering's operations, and upon receipt of notice or information of imprudent, illegal or unsound practices, to make a reasonable inquiry in connection therewith, and to take steps to correct such conditions or practices and make such disclosures as are necessary to comply with federal and state laws;
- (d) To exercise reasonable control and supervision over the Company's public statements to the securities markets by the officers and employees of Schering;
- (e) To supervise the preparation, filing and/or dissemination of any Securities and Exchange ("SEC") filings, press releases, audits, reports or other information required by law, to examine and evaluate any audits or other financial information concerning the financial condition of Schering and to cause Schering to obey and comply with and not violate the federal or state securities laws; and
- (f) To maintain and implement an adequate system of controls and information systems, such that no officer, director or employee of the Company would make false statements about Schering to the securities markets or would be able to or encouraged to violate federal or state laws restricting insider trading.
- 24. Defendants Becherer, Barclay, Herzlinger, Osborne, Van Oordt, and Weinbach, as members of the Company's Finance, Audit and Compliance

Committee, were able to and did, directly or indirectly, control the contents of the various financial reports and public filings with the SEC made on behalf of the Company during the relevant period. The Audit Committee members knew, or but for their gross negligence would have known, that statements in the Company's filing with the SEC were materially misleading. As a function of their responsibilities as members of the Audit Committee, these defendants knew, or but for a reckless or grossly negligent disregard of the truth would have known, that material adverse information concerning the Company, its financial condition and its prospects were not disclosed and thereby rendered the Company's public statements materially misleading. Indeed, as members of the Audit Committee, these defendants had access to internal corporate documents (including Schering's operating plans, forecasts and reports of actual operation), and had conversations and connections with corporate officers and employees, including internal auditing and financial managers, and received reports and other information in connection with their duties as Finance, Audit and Compliance Committee members.

25. Defendants participated in the decisions to release the false and misleading press releases and SEC filings complained of herein and/or were aware of, or recklessly disregarded, the misstatements contained therein and omissions therefrom. Defendants, because of their positions of control and authority as officers and/or directors of the Company, were able to and did control the contents of the SEC filings and press releases pertaining to the Company. Each of said defendants was provided with copies of Schering's press releases and SEC filings prior to or

shortly after their issuance and had the ability and opportunity to prevent their issuance or cause them to be promptly corrected.

- Finance, Audit and Compliance Committee of the Board and/or executive and managerial positions with Schering, each of the defendants had access to adverse non-public information about Schering's financial performance and condition, including the following facts: (i) Schering's receipt of four warning letters from the FDA regarding it manufacturing facilities; (ii) the repeated failure to fully comply with Good Manufacturing Practices ("GMP's") or other FDA regulatory standards; and (iii) defendants' failure to commit sufficient resources to redress the deficiencies in Schering's manufacturing facilities.
 - Schering to conduct its business in an unsafe, imprudent, illegal and/or dangerous manner by failing to timely or adequately correct deficiencies in the quality control and regulatory compliance functions of Schering's manufacturing facilities, by failing to fully and/or accurately report the Company's true financial condition and, by using non-public corporate information for their own personal benefit. Defendants' conduct, as detailed more fully herein, involves a knowing, culpable and/or reckless violation of their obligations as directors of Schering, an absence of good faith on their part, a reckless disregard for their duties to the Company and its shareholders in which the directors were aware or should have been aware of a risk of serious injury to the Company.

FACTUAL BACKGROUND

This action is brought by plaintiff derivatively on behalf of the Company, 28. to obtain relief for the breaches of fiduciary duty by defendants in grossly mismanaging the Company. Defendants, as Schering's board of directors during the year 2000, acted in violation of their fiduciary duties to properly manage the Company's manufacturing facilities. Specifically, defendants have failed to insure that Schering maintained basic health, quality, and management policies and procedures. As a result, Schering's manufacturing facilities, including those in Kenilworth and Union, New Jersey and those in Manati and Las Piedras, Puerto Rico, have been the subject of significant criticism by the United States Food and Drug Administration (the "FDA"). Indeed, some of the Company's pharmaceutical products have been so poorly produced that the Company has been required to recall them. As detailed more fully herein defendants cannot claim to have only just learned of these manufacturing deficiencies as the FDA has issued at least four Warning Letters to the Company in the past three years advising the Company of its failure to maintain GMP and failure to comply with Finished Pharmaceuticals regulations. The deficiencies cited by the FDA and other professionals auditing Schering's manufacturing processes were so fundamental and so pervasive that they could not and did not go unnoticed by defendants. However, defendants failed to take action with appropriate reasonableness. Instead of providing sufficient resources and policies to enforce detailed quality control, compliance and manufacturing guidelines, defendants maintained a corporate environment where employees were encouraged to deviate from or had insufficient resources to comply with GMP or Finished Pharmaceuticals regulations. As a result, Schering and its shareholders have been harmed by the serious damage to Schering's reputation occurring when Schering recalled its products and announced on February 16, 2001, that the FDA was withholding approval of CLARINEX (desloratadine), a Schering drug pending FDA approval, until the GMP deficiencies were resolved. In addition, Schering is the subject of securities fraud class actions because defendants allegedly failed to timely and adequately disclose the nature of the manufacturing deficiencies. Finally, defendants Kogan, Cesan, D'Andrade, Luciano, and Mundy each breached their duty of loyalty to the Company by usurping the undisclosed information regarding Schering's manufacturing quality deficiencies and FDA and other audit results to benefit themselves personally by trading in the Company's stock at artificially inflated prices.

29. In June of 1998, the FDA issued a warning letter to the General Manager of Schering's manufacturing facility in Las Piedras, Puerto Rico. The Warning Letter, which was not publicly disclosed by Schering at the time, advised Schering that upon its inspection, the FDA had documented deviations from GMP regulations and New Drug Application Field Alert Regulations of the FDA which caused the Company's Theo-Dur Extended Release Tablets to be classified by the FDA as "adulterated" and cautioning that the pending New Drug Applications "may not be approved" until the violations were corrected. Among the violations documented in the June 1998 Warning Letter were the: failure to account for manufacturing holding periods of up

to 18 months in ascribing expiration dates for drug packages, failure to conduct inprocess testing of all lots of intermediate materials used in the manufacturing
process, and failure to timely submit Field Alert Reports advising of the failure of
specific lots of drugs to satisfy quality testing. The defendants were aware of the
June 1998 Warning Letter or were grossly negligent in not becoming aware of the
Warning Letter during the period from June 2000 to February 2001.

On October 23, 1998, the FDA sent a Warning Letter to the President, Technical Operations of Schering. The October Warning Letter advised Schering that its manufacturing facilities in Union and Kenilworth, New Jersey also were found upon inspection to deviate significantly from GMPs and Finished Pharmaceutical regulations. The FDA also found that these deviations caused Schering's finished pharmaceuticals from these plants to be "adulterated" within the meaning of the Federal Food, Drug and Cosmetic Act. Among the problems cited by the FDA in the New Jersey plants were: lack of assurance that written production and process control procedures for coating Claritin-D 12 hour Repetabs are sufficient to produce a product that has the quality it is represented to possess; pan operators were using visual determinations of coating cycles rather than any written guideline for assessing whether coating solutions were evenly distributed; many batches were being rejected due to in-process dissolution failures; partial release of various products without data to validate to invalidate out-of-specification results from quality testing; mingling and subsequent packaging of one pallet of semi-finished bottles of rejected Nasonex nasal spray with bottles that were subsequently released in part; and lack of data to support the time period established to fill certain Proventil inhaler cans (noting that at least one batch was filled in excess of the specified hours and subsequently released).

October 1998 Warning Letter, Schering created a task force of representatives (in August or September 1998) from its Research, Quality Control and Manufacturing Operations to further evaluate the critical manufacturing parameters of Claritin-D12 Hour Repetabs and Proventil Repetabs. The FDA observed in the October Warning Letter that the task force appeared to be addressing the issues related to release criteria but still did not resolve the reasons for in-process dissolution failures. In addition, the FDA noted that as of October 1998, the FDA had not received a timetable from the task force as to when its evaluation would be completed." With respect to Schering's practice of partial releases, the FDA's October Warning Letter concluded:

Released products are expected to conform to established specifications from the beginning to the end of production. Current regulations specify that drug products failing to meet established standards or specifications and any other relevant quality control criteria shall be rejected. Reprocessing may be performed, provided certain criteria are met according to written procedures. The practice of partial releases, no matter how stringent the re-sampling, raises doubts as to the safety and efficacy of the product being released. It is not acceptable to substitute testing over adequate control of process.

32. On July 21, 1999, eight months after the October 1998 warning letter, Schering received another warning letter from the FDA regarding GMPs and Finished Pharmaceuticals regulations at Schering's Union and Kenilworth, New Jersey

facilities. Again, the deviations from applicable standards had caused Schering's finished pharmaceuticals to be "adulterated" within the meaning of the Federal Food, Drug and Cosmetic Act. Among the particular deviations cited by the FDA were: failure to reject finished drug products that did not meet established test specifications -- Vanceril DS Inhalation Aerosol; failure to follow written test procedures in nine batches of Vanceril DS Inhalers resulting in release of batches that did not satisfy written test procedures; and failure to subject Proventil (albuterol) Inhalation Aerosol to tests as required. The findings of this FDA inspection and Warning Letter forced Schering to cease distribution of Proventil Inhalation Aerosol. Schering representatives, including the Senior Vice President, Worldwide Regulatory Affairs met with members of the FDA to negotiate the conditions under which Schering could continue distribution, including a requirement that Schering submit to the FDA as a "Prior Approval" supplement, the results of new in-process test data on Proventil Inhalers. Schering did not publicly disclose the details of this or any of the other FDA Warning Letters until February 15, 2001.

33. On May 8, 2000, the FDA issued yet another Warning Letter to Schering advising it that the pharmaceutical products manufactured at Schering's Manati, Puerto Rico plant were "adulterated" within the meaning of the Federal Food, Drug and Cosmetic Act because Schering failed to follow GMPs. Among the findings of the May 2000 Warning Letter were: failure to perform adequate investigation into the cause of out-of-specification results for stability testing of Gentocin Opthalmic Solution; inadequate laboratory controls for documentation of Method Validation for

the stability assay method for Trilafon Injection, written specifications and to have the changes approved before implementation; failure to maintain complete data from all laboratory tests; failure to follow written procedures for cleaning equipment; failure to test drug product components to assure they meet current specifications; and failure to use reliable, meaningful and specific test methods for stability testing of drug products. Defendants were aware of each of the FDA Warning Letters or were grossly negligent in not becoming aware of the Warning Letters during the period from June 2000 to February 2001.

- 34. Because of defendants' repeated failure to act reasonably to address these deficiencies and their failure to require and enforce rigid compliance with GMPs and Finished Pharmaceuticals regulations, Schering was required to recall several of its products at least on September 9, 1999, December 2, 1999, and March 29, 2000. The number of inhalers actually recalled by Schering has been reported to be in excess of 59 million, costing Schering millions of dollars.
 - properly managing Schering's manufacturing processes and controls is further evidenced by the results of an inspection and audit performed by private consultants, evidenced by the results of an inspection and audit performed by private consultants, evidenced by the results of an inspection and audit performed by private consultants, evidenced by the results of an inspection and audit performed by private consultants, evidenced by the results of an inspection and audit performed by private consultants, evidenced by the results of an inspection and audit performed by private consultants, evidenced by the results of an inspection and audit performed by private consultants, evidenced by private consultants, evidenc

toward production". Problems with the Company's major money-making products— A Property of the second aerosols - were "indicative of insufficient technical expertise and managerial oversight". Indeed, the AAC report observed that,

this production area does not have the visibility and importance from an organizational standpoint that it needs in order to quickly and effectively recover from past problems, maintain satisfactory regulatory compliance, attract and retain necessary expertise, and grow in the

The absence of sufficient management oversight led to such gross deficiencies as the failure to perform an in-process assay for the active ingredient in Proventil. The AAC Consulting group recommended that,

upper management needs to demonstrate its long term commitment to product quality, such as through increased staffing/budget resource allocations and investments in new equipment, in order to supplant the traditional emphasis on production and firmly establish a company culture in which quality is, in fact, the number one priority.

Indicative of the absence of upper management's commitment to quality was the AAC's finding of unsanitary conditions in the Albuterol production area of the Kenilworth facility. Specifically, the AAC found,

Backup of sewage in the corridor adjacent to the room where albuterol solution for inhalation is manufactured has been occurring periodically over the last year or two without a plan for permanent correction and without any documentation of the problem or evaluation of product impact. During the early part of the audit, large pools of sewage were observed to form which were then tracked through the production facility. Ingredient containers and hoses came in contact with the floor and fecal organisms were observed to have a pathway to the product. Drugs produced in this area were not evaluated for exposure to fecal contamination.

- After the AAC report was delivered to Schering, defendants Kogan, Cesan, Luciano, Mundy and D'Andrade began to sell off large portions of the holdings of Schering stock based on the negative non-pubic information regarding Schering's grossly deficient manufacturing, quality control and regulatory compliance policies and procedures. Kogan sold 75,000 shares on December 15, 2000 for proceeds of \$4.35 million, and 105,769 shares on October 26, 2000 for proceeds of \$5.6 million. Defendant Cesan sold 44,500 shares on December 5, 2000 for proceeds of \$2.4 million, and 25,057 shares on November 21, 2000 for proceeds of \$1.3 million. Defendant D'Andrade sold 52,563 shares on October 9, 2000 for proceeds of \$2.4 million, 66,309 shares on November 21, 2000 for proceeds of \$3.5 million and 26,107 shares on December 6, 2000 for proceeds of \$1.39 million. Defendant Luciano sold 65,264 shares on October 9, 2000 for proceeds of \$3.1 million. Defendant Mundy sold 1,600 shares on December 29, 2000 for proceeds of \$91,104.
 - recommendations, defendants failed to act reasonably to assure that Schering established and enforced basic quality and regulatory compliance standards. Thus, on January 19, 2001, Schering's Senior Vice President Technical Operations for the Kenilworth Facility received a Form FDA 483 report of an inspection conducted by the FDA at Kenilworth. The report found that the manufacturing quality control and regulatory compliance deficiencies that had been repeatedly cited to Schering's regulatory compliance deficiencies still persisted. The FDA's findings pointed out

A

basic and fundamental problems highlighting how deficient defendants' management of the Company had become. Specifically, the FDA stated that:

The Quality Control Unit failed to assure that drug products were manufactured in compliance with GMPs and therefore have the safety, quality, and purity that they purport, or are represented to possess. The Quality Control Unit failed to uphold their responsibilities to assure valid performance of manufacturing processes, suitability or equipment, support systems, and analytical methods for their intended use, and prevention of contamination through proper cleaning procedures.

Among the other findings of the FDA report were: the Validation Department and Quality Control Unit "routinely generate and approve protocols and reports, which contain critical deficiencies; laboratory and manufacturing deviations were not adequately investigated according to written procedures, and in a way that provides a timely and scientific conclusion on which to base the disposition of a batch; Product Quality Review methods for the Delivery of Albuterol through the Actuator and Particle Size for Proventil Aerosol Inhaler were inadequate in that the methods exhibit various unidentified extraneous peaks; absence of assurance that manufacturing process, parameters, equipment, or protocols and their acceptance criteria at multiple sites for production of Clarinex are equivalent or capable of producing product of the same quality. These findings reflect the complete failure of defendants to adequately and reasonably manage the Company. Rather than beginning in 1998 to address the fundamental absence of a quality and compliance priority in the manufacturing facilities, defendants chose to emphasize production at the expense of quality and compliance. The FDA has advised Schering that it will not 19

be allowed to gain approval or start shipping its new allergy drug, Clarinex until the FDA is satisfied that these issues have been addressed.

- Oompliance and Audit Committee or the Company's Board of Directors and/or as directors, were aware of or were grossly negligent and in violation of their fiduciary duties in not becoming aware of the persistent, prevalent and grossly deficient quality control standards and inadequate regulatory compliance procedures utilized in the Company's manufacturing facilities for the Company's highest money-making products. Defendants, as the Company's senior-most management and directors of the Company were also responsible for creating a corporate culture in which production and profitability were valued greater than quality, safety and regulatory compliance. Defendants failed to provide adequate resources to assure that the Company could effectively maintain the quality of its product and production facilities.
 - 40. Defendants also acted in breach of their fiduciary duties of candor and due care by failing to fully disclose in the Company's financial reporting with the SEC, the full extent and impact of the deficiencies in Schering's manufacturing facilities. Instead, defendants concealed this material information in order to artificially inflate the price of Schering's stock and to maintain their positions with the artificially inflate the price of Schering's stock and directors have now been named as Company. Schering and certain of its officers and directors have now been named as defendants in various federal securities law class actions and the Company is

. . . .

subjected to millions of dollars of potential liability in connection with those securities law claims.

DERIVATIVE ALLEGATIONS

- Plaintiff brings this action derivatively in the right and for the benefit of Schering to redress injuries suffered and to be suffered by Schering as a direct result 41. of the breaches of fiduciary duty and violations of laws alleged herein. Plaintiff will adequately and fairly represent the interests of Schering and its shareholders in enforcing and prosecuting their rights.
 - Plaintiff has not made any demand on the Board to institute this action. 42. Demand is excused here because it would be a futile and useless act.
 - A majority of Schering's current board, as senior executives or members of the Finance, Audit and Compliance Committee of the Board of Directors, were 43. directly responsible for mismanaging the quality control, regulatory compliance and sound auditing of the Company's manufacturing facilities. Defendants Kogan, and Cesan, as senior executives of the Company had access to and a duty to know about such important facts as the issuance of four FDA Warning Letters over the course of two years and were aware that the reasons for the product recalls had not been fully resolved but that defendants had instead directed the Company in such a way that production took precedence over quality. Defendants Becherer, Barclay, Herzlinger, Osborne, VanOordt and Weinbach, as members of the Finance, Audit and Compliance Committee of the Board of Directors, were responsible for overseeing the Company's internal audit function and business conduct policy. As such, these defendants were

ميالا والمراج

directly responsible for failing to assure that Schering had in place adequate systems to timely identify and correct manufacturing quality deficiencies before defective products were put into the marketplace in violation of FDA standards. All of the defendants, as directors of Schering, are also directly liable for breaching their duty of care by failing to take sufficient steps after receiving the FDA Warning Letters to totally revise Schering's approach to quality and regulatory compliance. Instead, defendants acted with gross negligence in allowing the Company to continue to operate manufacturing facilities that failed to satisfy basic quality, safety and sanitary regulations and/or standards. In addition, defendants Kogan, Cesan, Luciano, and Mundy are liable for breaching their duty of loyalty by trading in Schering stock based on non-public information.

of persons who are alleged herein as principal wrongdoers having acted with actual knowledge of wrongdoing. The Directors all were personally and directly involved in the acts of mismanagement and/or disloyalty alleged herein. Consequently, the entirety of Schering's Board has direct and personal financial interests in the outcome of the litigation and the alleged wrongdoing that prevent them from exercising an unbiased business judgment as to whether to proceed with this action. In order to bring this action, the Board would have been required to sue not only themselves but also their fellow directors and allies in the top ranks of the Company with whom they have personal and business relationships and with whom they have entangling financial alliances, interests and dependencies.

45. The acts complained of herein constitute violations of law, breaches of the fiduciary duties owned by defendants and waste of corporate assets. Such acts are legally incapable of ratification.

No sell of

- of the defendants named herein with violations of certain securities laws arising from many of the same wrongful acts alleged herein. Therefore, by determining to fight the class actions, the Board has already expressed its conclusion that most of the transactions complained of herein and the Company's directors and officers' actions with regard to such transactions are and were proper, and that the claims asserted in this action are without merit and should not be pursued by the Company. Accordingly, an action asserting substantially similar claims to those asserted in this action would not and could not be initiated, continued or vigorously pursued on behalf of the Company if a formal demand were made upon the Board.
- 47. Since the class actions charge the Company and the defendants named herein with violations of the federal securities laws arising from many of the same wrongful transactions alleged herein, the Board would be required to undermine Schering's defense in the class actions in order to prosecute the claims asserted in this action. For these reasons, the Board could neither exercise good faith nor independent objective judgment in deciding whether to bring this action, nor vigorously prosecute this action.
- 48. At all relevant times, the Board operated as a collective entity through periodic meetings held either in person or telephonically where they discussed

A . 15 # F

matters affecting the Company's business and reached collective and consensual decisions regarding actions taken. The Board members were fully informed of the facts alleged herein and could not have reasonably believed that their conduct was in conformity with the GMPs or other applicable regulations. With respect to the breaches of loyalty resulting from trading on inside information, defendants did not act with the best interest of the Corporation in mind. Rather, they subjected the Corporation to attack and sought to reap personal financial gain. As a result, the acts which defendants both explicitly and tacitly approved cannot be the product of a valid business judgment.

COUNTI

Against All Defendants for Breach of Fiduciary Duty

- 49. Plaintiff incorporates by reference each of the foregoing allegations.
- 50. The defendants owed to Schering the highest duties of loyalty, honesty, diligence and fairness in conducting the Company's affairs in a lawful manner. The defendants knowingly or with gross recklessness breached their fiduciary duties by orchestrating, devising, carrying out, participating in and/or failing to prevent, terminate, or timely correct the wrongdoing alleged herein, which included:
- (1) directing the business and operations of Schering in such a manner as to put production before quality and regulatory compliance;
- (2) failing to assure that adequate resources, systems, policies, and procedures were in place to assure that Schering's manufacturing facilities could comply with GMPs and other FDA regulations;

- (3) failing to respond in a timely and effective manner to the repeated Warning Letters from the FDA and the report of the AAC;
- (4) allowing directors and senior officers of Schering to trade in the Company's stock while in possession of material non-public information; and
- (5) making false and misleading statements to the public and/or concealing material and adverse information subjecting the Company to liability for violation of the federal securities law.
- 51. Each of these violations was achieved because defendants willingly, knowingly and/or with gross recklessness allowed Schering to continue, despite several warnings from the FDA to operate without adequate policies or procedures in place to assure that violations of federal regulations or guidelines were not made in the manufacture of the Company's pharmaceutical products. Any purported warnings issued by the Company or any defendant that generally discussed the risks faced by Schering as a result of the manufacturing facilities' deficiencies were not sufficient and concealed from the public that Schering failed to follow acceptable policies and procedures for maintaining production quality and compliance with applicable regulatory standards.
- 52. As a direct and proximate result of the defendants' violations of their fiduciary duties, Schering has been injured. Schering's reputation for conducting and/or supporting effective, accurate and ethical manufacture of pharmaceutical products has been permanently tarnished. Schering's development and marketing of Clarinex will be postponed because the FDA will not grant approval to the drug until

the GMP deficiencies at the Company's manufacturing facilities are resolved. Schering has been forced to shut down a number of its production lines in order to undertake drastic changes to better meet the GMPs and other regulatory standards. Schering has been named as a defendant in numerous federal securities law class action lawsuits as a direct result of their failure to fully disclose to the public the depths of Schering's GMP deficiencies. Schering has been injured to the extent it has already had to respond to these suits and will continue to incur the expense of litigation as well as the risk of judgment because of defendants' wrongful conduct alleged herein. The exact amount of Schering's total damages are not presently determinable.

- 53. Plaintiff also seeks to recover from defendants Kogan, Cesan, Luciano, Mundy and D'Andrade for their breaches of their duty of loyalty by usurping non-public corporate information for their own personal gain. Under applicable law, plaintiffs are entitled to have these defendants disgorge their ill-gotten gains in illegal trading in Schering stock. To date, neither defendants nor the Company have made any effort to recoup, on the Company's behalf, the illegal profits obtained by defendants' insider trading. The Company is entitled to recover these improperly obtained profits regardless of whether the Company suffered any damages.
- 54. Plaintiff brings this action as a current shareholder of Schering on behalf of Schering to obtain indemnification for all damages suffered by Schering and a judicial determination that each of the defendants is obligated to indemnify and hold Schering harmless from any and all such damages, judgments or other awards,

including attorneys' and expert fees, that may be recovered against Schering in any litigation relating to the defendants' breaches of duty, including the federal securities law class actions. Further, plaintiff, on behalf of Schering seeks recovery of all damages suffered by Schering as a result of defendants' breaches of duty.

WHEREFORE, plaintiff demands judgment as follows:

- (a) Awarding compensatory damages or money damages against all defendants, jointly and severally, in favor of Schering for all losses and damages suffered as a result of the acts and transactions complained of herein, together with pre-judgment interest from the day of the wrongs to the day of judgment herein;
- (b) Declaring that the defendants, and each of them, have committed a gross abuse of trust and have breached their fiduciary duties to Schering;
- (c) Declaring that the defendants are obligated to indemnify and hold Schering harmless from any fines, penalties, judgment, settlement or award pursuant to any of the class actions pending or to be filed against Schering or its employees or agents arising out of the breaches of duty and wrongdoing alleged herein;
- (d) Declaring that each of the insider trading defendants be compelled to disgorge the proceeds of their trading based on inside information and that the Company recover such proceeds to prevent the defendants from being unjustly enriched by their breach of duty;
- (e) Directing that all defendants account for all damages caused by them as a result of their unlawful conduct;

- (f) Awarding plaintiff its costs and expenses for this action, including reasonable attorneys' and experts' fees; and
- (g) Granting such other and further relief as this Court may deem just and proper.

Dated:

marker to be

March 20, 2001

JOSEPH R. SANTOLI, ESQ.

Joseph R. Santoli 615 Franklin Turnkpike Ridgewood, New Jersey 07450 201-444-2888

SQUITIERI & FEARON, LLP LEE SQUITIERI 521 Fifth Avenue New York, New York 10175 646-487-3049

LAW OFFICES OF BERNARD M. GROSS, P.C. Bernard M. Gross
Deborah R. Gross
Christopher T. Reyna
1500 Walnut Street, 6th Floor
Philadelphia, PA 19102
(215) 561-3600

Attorneys for Plaintiff

<u>VERIFICATION</u>

Richard Pendolphia, on behalf of the Laborer's Tri-County Pension Fund does hereby verify that the facts set forth in the foregoing Derivative Complaint are true and correct to the best of his knowledge, information and belief.

This statement is made subject to the penalties of perjury under the laws of the United States of America.

Date: MARCH 15, 2001

RICHARD PENDOLPHIA